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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,992	06/09/2005	Hiroshi Matsui	081356-0243	1370

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EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/537,992	MATSUI, HIROSHI	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All objections and rejections not repeated in the instant Action have been withdrawn due to the Applicant's response to the previous action.

Claims 1-12 are pending in this application.

Claim Rejections - 35 USC § 103

Claims 1-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Suguichi (US 6,794,157 B1).

This rejection is maintained for reasons of record set forth in the action mailed 03/30/06, (slightly altered to take into consideration Applicant's amendment filed 06/30/06) repeated below:

Sugiuchi teaches a method for measuring cholesterol in low density lipoprotein (LDL) and high density lipoprotein (HDL) in a biological sample with a single measurement, and HDL and total cholesterol (HDL, LDL, VLDL and CM) in a biological sample with a single measurement (Column 13, Lines 15-66 and Column 14, Lines 1-54).

Sugiuchi teaches a method wherein the first step comprises reacting cholesterol in lipoproteins other than LDL in a biological sample, and a second step in which cholesterol in the remaining LDL is reacted (Column 10, Lines 16-28).

Sugiuchi teaches a method wherein a first measurement value reflecting the existing amount of cholesterol in lipoproteins other than the LDL in a biological sample (HDL) and a second measurement value reflecting the existing amount of cholesterol in the LDL, are obtained with a single measurement (Column 12, Lines 38-49) and then the existing amounts of cholesterol in the LDL and HDL cholesterol in the biological sample are simultaneously measured based on the two previous values (Column 12, Lines 38-59).

Sugiuchi teaches a method wherein in the presence of a surfactant acting on lipoproteins other than LDL (Column 21, Claims 6,9 and 11), the first step comprises causing cholesterol esterase and cholesterol oxidase to act on lipoproteins other than the LDL in a biological sample (Column 21, Claim 6 and Column 22, Claim 12), and then measuring the generated NADH (Column 12, Lines 5-60 and Column 9, Lines 21-57) and causing cholesterol esterase and cholesterol oxidase to act on lipoproteins other than the LDL in a biological sample, converting the generated hydrogen peroxide into a quinine dye and then measuring the resultant (Column 21, Claim 6 and Column 9, Lines 11-16).

Sugiuchi teaches a method wherein the second step comprises adding a surfactant (Column 12, Lines 24-25) acting at least on the LDL to the reaction product of the first step, causing cholesterol esterase and cholesterol oxidase to act on the remaining LDL and then measuring generated NADH (Column 12, Lines 5-60 and Column 9, Lines 47-57).

Suguichi teaches a method on which analysis is carried out with a single measurement using an automated analyzer (Column 15, Lines 32-40).

Sugiuchi teaches a method wherein cholesterol in LDL in blood is quantified by finding the difference between absorbances obtained as measurement values in the first and second steps (Column 12, Lines 55-59).

Sugiuchi teaches a method wherein total cholesterol is quantified by finding total absorbance based on a change in absorbance obtained as a measurement value in the first step and a change in absorbance as a measurement value in the second step (Column 14, Lines 39-43).

Sugiuchi teaches a reagent composition for simultaneously measuring cholesterol in HDL and LDL and total cholesterol in a biological sample (Column 13, Lines 54-66 and Column 14, Lines 1-44).

Sugiuchi teaches a reagent composition which comprises a surfactant acting on lipoproteins other than LDL, a surfactant acting on at least LDL, cholesterol esterase, and cholesterol oxidase (Column 13, Lines 15-51).

Sugiuchi teaches a reagent composition which comprises the surfactant acting on lipoproteins other than LDL, the surfactant acting on at least LDL, cholesterol esterase, and cholesterol oxidase (Column 13, Lines 15-51).

Suguichi does not teach the simultaneous measurement of LDL and total cholesterol in a biological sample.

It would have been obvious to one of ordinary skill in the art at the time of the invention to adapt the methods of Suguichi for the simultaneous determination of low density lipoprotein (LDL) and high density lipoprotein (HDL) in a biological sample with a single measurement, and HDL and total cholesterol (HDL, LDL, VLDL and CM) in a biological sample with a single measurement to the determination of LDL and total cholesterol in a biological sample because Suguichi already teaches the determinations of LDL and total cholesterol in separate assays. One of ordinary skill in the art would have been motivated to make this change in order to have a ratio determination of LDL ("Bad" cholesterol) to total cholesterol as this is an important value in clinical diagnosis of lipid-related disease. There would have been a reasonable expectation of success in making this change because Suguichi already taught the determination of LDL and total cholesterol in similar methods.

Response to Arguments

Applicant argues that Suguichi teaches two embodiments: the "continuous fractional determination" of HDL and LDL cholesterol within the same biological sample and the "continuous fractional determination" of LDL and total cholesterol within the same biological sample whereas the instant application is directed to a method of determining LDL and total cholesterol, not HDL and total cholesterol within the same sample (Remarks, Pg. 5, Paragraphs 1 and 2).

This is not found persuasive because it would have been obvious to combine the two fractional determinations into a single embodiment of the determination of LDL and total cholesterol in the same biological sample. See the rejection above.

Applicant argues that Suguichi teaches determining HDL cholesterol, in part by sequestering non-HDL particles whereas the instant invention does not involve sequestration but targets subsets of lipoprotein by using specific surfactants.

This is not found to be persuasive because the claims only states a method wherein, "in the presence of a surfactant acting on lipoproteins other than LDL..." Claim 5, "...adding a surfactant acting at least on the LDL to the reaction product of the first step..." Claim 6, "A reagent composition which comprises a surfactant acting on at least the LDL, cholesterol esterase and cholesterol oxidase" Claims 11 and 12. Suguichi clearly teaches the use of a composition containing a surfactant which acts on LDL, cholesterol esterase and cholesterol oxidase (Column 12, Lines 20-27 and Lines 43-47), as well as a surfactant acting on lipoproteins other than LDL (Column 13, Line 27).

Applicant argues that the total cholesterol value is calculated with not only the LDL and HDL cholesterol, but also VLDL and CM values, and thus combining only LDL and HDL will not provide the correct total cholesterol value.

This is acknowledged as correct, however the obviousness rejection is still maintained.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence or evidence to the contrary.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1655

08/30/06

CHRISTOPHER R. TATE
PRIMARY EXAMINER